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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,565	09/27/2006	Tarja Laitinen	0933-0249PUS1	4520

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EXAMINER	
LANDSMAN, ROBERT S	

ART UNIT	PAPER NUMBER
1647	

NOTIFICATION DATE	DELIVERY MODE
01/12/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/539,565	LAITINEN ET AL.	
	Examiner	Art Unit	
	ROBERT LANDSMAN	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-119* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-119* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Lack of Unity

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-7 and 110-116, drawn to an isolated GPRA polypeptide and a pharmaceutical composition thereof.

Group II, claims 1-23, drawn to an isolated nucleic acid or genomic DNA encoding GPRA, a vector and host cell.

Group III, claim 24, drawn to an antibody.

Group IV, claims 25-31, drawn to a method of preventing or treating asthma by administering a modulator of GPRA polypeptide.

Group V, claims 32-33, drawn to a method of identifying a modulator of a GPRA polypeptide.

Group VI, claims 34-48, drawn to a method of determining the risk of asthma by determining a polymorphic GPRA gene.

Group VII, claims 49-55, drawn to a method of identifying a polymorphic site within a GPRA gene.

Group VIII, claims 56-61 and 66-69 drawn to a primer or probe and a kit.

Group IX, claims 62-65, drawn to a transgenic animal.

Group X, claims 70-73 and 117-119, drawn to an isolated AAA1 polypeptide and a pharmaceutical composition thereof.
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Group XI, claims 74-84, drawn to an isolated nucleic acid or genomic DNA encoding AAA1, a vector and host cell.

Group XII, claim 85, drawn to an antibody.

Group XIII, claims 86-88, drawn to a method of preventing or treating asthma by administering a modulator of AAA1.

Group XIV, claims 89-90, drawn to a method of identifying a modulator of AAA1.

Group XV, claims 91-97, drawn to a method of determining risk of asthma by determining a polymorphic AAA1 gene.

Group XVI, claims 98-103, drawn to a method of identifying a polymorphic site within an AAA1 gene.

Group XVII, claims 104-107, drawn to a primer or probe.

Group XVIII, claims 108-109, drawn to a transgenic animal.

B. The inventions listed as Groups I-XVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is an isolated polypeptide at least 90% identical to SEQ ID NO:3, which is anticipated by Matsumoto et al. (WO200148188). Matsumoto teach a polypeptide 100% identical to SEQ ID NO:3 of the instant invention.(see sequence comparison below). Therefore, Group I lacks novelty or inventive step and does not make a contribution over the prior art.

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ID   AAG64118 standard; protein; 371 AA.
XX
AC   AAG64118;
XX
DT   15-JUN-2007  (revised)
DT   25-SEP-2001  (first entry)
XX
DE   Human G protein-coupled receptor GPRv8.
XX
OS   Homo sapiens.
XX
PN   WO200148188-A1.
XX
PD   05-JUL-2001.
XX
PF   28-DEC-2000; 2000WO-JP009408.
XX
PR   28-DEC-1999;   99JP-00375152.
PR   31-MAR-2000; 2000JP-00101339.
XX
PA   (HELI-) HELIX RES INST.
XX
PI   Matsumoto S,  Oda T,  Saito Y,  Morikawa N,  Yoshida K,  Suwa M;
PI   Sugiyama T,  Kishimoto T,  Kanzaki K,  Yasuda S,  Inoue Y;
XX
DR   WPI; 2001-425662/45.
DR   N-PSDB; AAH73501.
DR   PC:NCBI; gi46395496.
DR   PC:SWISSPROT; Q6W5P4.
XX
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PT   New DNA encoding guanosine triphosphate binding protein coupled receptors
PT   and their expression products for screening potential anticancer and
PT   nootropic drugs and in diagnosis of these diseases.
XX
PS   Claim 1; Page 102-104; 170pp; Japanese.
XX
CC   The invention relates to nine human guanosine triphosphate binding
CC   protein (G protein)-coupled receptors designated GPRv8, GPRv12, GPRv16,
CC   GPRv21, GPRv40, GPRv47, GPRv51, GPRv71 and GPRv72, and to the genes
CC   encoding them. These genes and proteins and antibodies against the
CC   protein are useful in the treatment, prevention, diagnosis and
CC   investigation of diseases associated with G protein-coupled receptors,
CC   including cancer, cirrhosis of the liver and Alzheimer's disease. The
CC   present sequence is a G protein-coupled receptor of the invention
CC
CC   Revised record issued on 15-JUN-2007 : Enhanced with precomputed
CC   information from BOND.
XX
SQ   Sequence 371 AA;

  Query Match             100.0%;  Score 1934;  DB 4;  Length 371;
  Best Local Similarity   100.0%;  Pred. No. 9.1e-199;
  Matches  371;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 MPANFTEGSFDSSGTGQTLDSSPVACTETVTFTEVVEGKEWGSFYYSFKTEQLITLWVLF 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MPANFTEGSFDSSGTGQTLDSSPVACTETVTFTEVVEGKEWGSFYYSFKTEQLITLWVLF 60

Qy         61 VFTIVGNSVVLFSTWRRKKKSRMTFFVTQLAITDSFTGLVNILTDINWRFTGDFTAPDLV 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 VFTIVGNSVVLFSTWRRKKKSRMTFFVTQLAITDSFTGLVNILTDINWRFTGDFTAPDLV 120

Qy        121 CRVVRYLQVVLLYASTYVLVSLSIDRYHAIVYPMKFLQGEKQARVLIVIAWSLSFLFSIP 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 CRVVRYLQVVLLYASTYVLVSLSIDRYHAIVYPMKFLQGEKQARVLIVIAWSLSFLFSIP 180

Qy        181 TLIIFGKRTLSNGEVQCWALWPDDSYWTPYMTIVAFLVYFIPLTIISIMYGIVIRTIWIK 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 TLIIFGKRTLSNGEVQCWALWPDDSYWTPYMTIVAFLVYFIPLTIISIMYGIVIRTIWIK 240

Qy        241 SKTYETVISNCSDGKLCSSYNRGLISKAKIKAIKYSIIIILAFICCWSPYFLFDILDNFN 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 SKTYETVISNCSDGKLCSSYNRGLISKAKIKAIKYSIIIILAFICCWSPYFLFDILDNFN 300

Qy        301 LLPDTQERFYASVIIQNLPALNSAINPLIYCVFSSSISFPCREQRSQDSRMTFRERTERH 360
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        301 LLPDTQERFYASVIIQNLPALNSAINPLIYCVFSSSISFPCREQRSQDSRMTFRERTERH 360

Qy        361 EMQILSKPEFI 371
              ||||||||||| 
Db        361 EMQILSKPEFI 371
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C. The inventions listed as Groups I-XVIII do not meet the requirements for Unity of Invention or the following reasons:

Groups I-III, VIII, IX, X-XII, XVII, XVIII are drawn to separate, distinct inventions and are distinguished from each other because the special technical features which define them by chemical and physical characteristics i.e. structure/function, as well as biological functions are different and these special technical features are not shared by each invention. Since these special technical features are not shared by each product and since the common features do not establish an advance over the prior art, the inventions do not form a single inventive concept within the meaning of Rule 13.2

Groups IV-VII, XIII-XVI are drawn to methods different in design and performance, and which do not share the same or a corresponding special technical feature which define the contribution of each invention. The methods of Groups III-V do not share a corresponding special technical feature because the methods are practiced with materially different process steps for materially different purposes and each method requires different starting materials, process steps and goals. Since these special technical features are not shared by each process, and since the common features do not establish an advance over the prior art, the inventions do not form a single inventive concept within the meaning of Rule 13.2.

The invention of Groups I-III, VIII, IX are separate and distinct from the invention of Groups XIII-XVI because the invention of Group I-III, VIII, IX may be used in other methods than those of Groups XIII-XVI.

The invention of Groups X-XII, XVII, XVIII are separate and distinct from the inventions of Groups IV-VII because the invention of Groups X-XII, XVII, XVIII are not used or produced by the inventions of Groups IV-VII.

The invention of Group II is separate and distinct from the invention of Groups IV, V because the invention of Group II may be used in other methods than those of Groups IV, V.

The invention of Group III is separate and distinct from the invention of Groups IV-VII because the invention of Group III may be used in other methods than those of Groups IV-VII.

The invention of Group XI is separate and distinct from the invention of Groups XIII, XIV because the invention of Group XI may be used in other methods than those of Groups XIII, XIV.

The invention of Group XII is separate and distinct from the invention of Groups XIII-XVI because the invention of Group XII may be used in other methods than those of Groups XIII-XVI.

D. **In order to be fully responsive**, in addition to electing a Group, Applicants must elect, as appropriate, a specific SEQ ID NO of either –

(1) a GPRA polypeptide
(2) a GRPA nucleic acid
(3) a AAA1 polypeptide, or
(4) a AAA1 nucleic acid

As appropriate, Applicants must also elect specific variants shown in the different Tables (e.g. claim 5 where the polypeptide includes a specific amino acid from Table 7). A similar situation is seen in claims 6 and 7 where a specific substitution is desired. In other words, Applicants must elect a single polymorphism to be searched.

In short, any Group reciting more than one SEQ ID NO, or possible amino acid or nucleic acid substitution which can be selected either as recited in a claim and/or in a Table must be limited in this Restriction to a single SEQ ID NO.

If Applicants elect a single polymorphism, and that sequence is found allowable, then any polymorphisms comprising that SNP will also be considered for allowance.

E. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman, Ph.D. whose telephone number is (571) 272-0888. The examiner can normally be reached on M-F 10 AM – 6:30 PM (eastern).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert Landsman/
Primary Examiner, Art Unit 1647